K002484

OCT - 4 2000

510(k) Summary
for
EMS SWISS ORTHOCLAST® Chisels for Non-cemented Prosthesis Removal

1. SPONSOR

EMS SA
Ch. de la Vuarpillière 31
CH-1260 Nyon
Switzerland

Contact Person: Gianni Campana
Telephone: 011 41 22 9944770

Date Prepared: August 11, 2000

2. DEVICE NAME

Proprietary Name:	EMS SWISS ORTHOCLAST® Extraction Tools
Common/Usual Name:	Accessories to Powered orthopedic surgical instrument
Classification Name:	Instrument, surgical, orthopedic, pneumatic powered and accessories

3. PREDICATE DEVICE

EMS SWISS ORTHOCLAST® (K991588)

4. Intended Use

The chisels and extraction sleeve described in this Special 510(k) are intended for use as accessories to the EMS SWISS ORTHOCLAST® for the removal of non-cemented prostheses during implant revision surgery.

5. Device Description

This Special 510(k) describes chisels to be used with the EMS SWISS ORTHOCLAST® for removal of non-cemented prostheses during implant revision surgery. The chisel tips are designed to remove prostheses with both macrostructured and

microstructured surface types. The chisel shaft is a thin, flexible blade, designed to follow the surface of the prosthesis along a straight or convex side. All chisels are made of the same medical grade stainless steel as those previously described in K991588 for cemented prosthesis removal. The chisels are connected to the ORTHOCLAST® handpiece using the same screwcap as described in K991588. A silicone sleeve at the proximal end of the chisel, also described in K991588, provides a watertight seal between the chisel and handpiece and serves as a shock absorber.

Removal of the chisel following insertion is facilitated by use of an extraction sleeve and a split mallet. The extraction sleeve is secured to the proximal end of the chisel by use of a locking mechanism. The split mallet is then attached to the extraction sleeve to hammer out the chisel. Both of these accessories are made of surgical grade stainless steel.

6. Basis for Substantial Equivalence

The EMS SWISS ORTHOCLAST® extraction tools described in this Special 510(k) are substantially equivalent to the extraction tools previously described for the EMS SWISS ORTHOCLAST® in K991588. The chisels for non-cemented prosthesis removal are made of the same materials and operate using the same mechanism as those for cemented prosthesis removal. Documentation of the EMS Design Control procedures, a risk analysis for the modified chisels, and a summary of the testing done to validate the modifications were provided to support the substantial equivalence of the EMS SWISS ORTHOCLAST® extraction tools for removal of non-cemented prostheses during implant revision surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 4 2000

Ms. Sheila Hemeon-Heyer, J.D., RAC
Senior Staff Consultant
MDCI Representing EMS SA
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K002484
Trade Name: Swiss OrthoClast® Chisels for Non-cemented Prosthesis Removal
Regulatory Class: II
Product Code: JDX, HSZ, LZV and GET
Dated: August 11, 2000
Received: August 14, 2000

Dear Ms. Hemeon-Heyer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002484

Device Name: EMS SWISS ORTHOCLAST® Chisels for Non-cemented Prosthesis Removal

Indications For Use:

The chisels and extraction sleeve described in this Special 510(k) are intended for use as accessories to the EMS SWISS ORTHOCLAST® for the removal of non-cemented prostheses during implant revision surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002484

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)